



CORTISPORIN® OTIC SUSPENSION Sterile (POLYMYXIN B-NEOMYCIN-HYDROCORTISONE)

DESCRIPTION: Each ml contains: Aerosporin® (Polymyxin B Sulfate) 10,000 units, neomycin sulfate 5 mg (equivalent to 3.5 mg neomycin base), hydrocortisone 10 mg (1%). The vehicle contains the inactive ingredients cetyl alcohol, propylene glycol, polysorbate 80, water for injection and thimerosal (added as a preservative) 0.01%. Sulfuric acid may be added to adjust pH.

ACTION: Hydrocortisone, the naturally occurring adrenal corticosteroid, affords antiallergic, antipruritic and anti-inflammatory activity.

Polymyxin B is one of a group of closely related substances produced by various strains of *Bacillus polymyxa*. Its activity is sharply restricted to gram-negative bacteria, including many strains of *Pseudomonas aeruginosa*.

Neomycin, isolated from *Streptomyces fradiae*, has antibacterial activity *in vitro* against a wide range of gram-negative and gram-positive organisms, with effectiveness against many strains of *Proteus*.

INDICATIONS: For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics, and for the treatment of infections of mastoidectomy and fenestration cavities caused by organisms susceptible to the antibiotics.

CONTRAINDICATIONS: This product is contraindicated in those individuals who have shown hypersensitivity to any of its components, and in herpes simplex, vaccinia and varicella.

WARNINGS: As with other antibiotic preparations, prolonged treatment may result in overgrowth of non-susceptible organisms and fungi.

If the infection is not improved after one week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed.

When using neomycin-containing products to control secondary infections in the chronic dermatoses, such as chronic otitis externa, it should be borne in mind that the skin in these conditions is more liable than is normal skin to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low grade reddening with swelling, dry scaling and itching; it may be manifest simply as a failure to heal. During long-term use of neomycin-containing products, periodic examination for such signs is advisable and the patient should be told to discontinue the product if they are observed. These symptoms regress quickly on withdrawing the medication. Neomycin-containing applications should be avoided for that patient thereafter.

PRECAUTIONS: If sensitization or irritation occurs, medication should be discontinued promptly.

This drug should be used with care in cases of perforated eardrum and in longstanding cases of chronic otitis media because of the possibility of ototoxicity caused by neomycin.

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Patients who prefer to warm the medication before using should be cautioned against heating the suspension above body temperature, in order to avoid loss of potency.

Treatment should not be continued for longer than 10 days.

Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin, paromomycin, streptomycin, and possibly gentamicin.

ADVERSE REACTIONS: Neomycin is a not uncommon cutaneous sensitizer. There are articles in the current literature that indicate an increase in the prevalence of persons sensitive to neomycin.

DOSAGE AND ADMINISTRATION: The external auditory canal should be thoroughly cleansed and dried with a sterile cotton applicator.

The patient should be instructed to avoid contaminating the dropper with material from the ear, fingers, or other source. This caution is necessary if the sterility of the drops is to be preserved.
SHAKE WELL BEFORE USING.

HOW SUPPLIED: Bottle of 10 ml with sterilized dropper.

ALSO AVAILABLE: Cortisporin Otic Solution bottle of 10 ml with sterilized dropper.